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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	8066-057	6851
28765	7590	11/30/2005		
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/692,123	Applicant(s) LESCH, PAUL R.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/10/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13 and 15-30 is/are rejected.
- 7) ☐ Claim(s) 5,13,16 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/2000</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments

In reference the current status of this application applicant is advised of the following. Currently claims (submitted August 31, 2004) 1-7, 9-13, 15-30 are pending, with claims 8 and 14 cancelled by Applicant.

In reference to the May 03, 2002 office action Applicant elected claims drawn to the present invention (Figures 7-10), this invention has been constructively elected by original presentation for prosecution on the merits.

Applicant's arguments, see Applicants Remarks, filed August 31, 2004, with respect to the withdrawal of claims 18-22 (drawn the method) and claims 23-28 have been fully considered and are persuasive. The withdrawal of claims 18-28 has been withdrawn and are now pending as previously stated.

Applicant's arguments with respect to claims 1-7 (incorrectly numbered as "17" in Applicants Remarks", 9-13 and 15-17 have been considered but are moot in view of the new ground(s) of rejection.

In conclusion the Applicants Remarks also indicate a response to a final status of this application. As currently stands this application is still in a non-final state, this serves as official notice.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 20, 2000 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "injection device" must be shown or the feature canceled from the claims 13, 16, and 22. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 5 is objected to because of the following informalities: examiner believes that claim 5 appears to be a copy of claim 3, they both depend from independent claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-13, 15-17, 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed in the Response to Arguments the term "jet injector" has been added to the specification and claims without due description. The abstract and specification are silent to the definition of a "jet injector." By applicants own admission the "jet injector" is structurally different and therefore is consider new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 9- 13, 16, 18-20, 23-27, and 30 are rejected under 35

U.S.C. 102(b) as being anticipated by Malay et al. (5,415,648). Malay et al. discloses a multi-purpose syringe injector with a cylindrical tube and two stoppers. The first stopper being movable in the tube (38) and shaped to meet the second stopper (34) also being movable within said tube. A beveled needle is present (22) that is operative communication with the second end of the tube and can pierce the first stopper when pressure is applied to the system via the injection device (50) and expel the medicament present in the tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 ,17, 21, 22, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malay et al. in view of Sudo (5,637,100). Malay et al.

Art Unit: 3763

discloses the claimed invention except for the third stopper, enlarged diameter, and mixing scheme between the third stopper and diameter. Sudo teaches that it is known to use an additional stopper (8) and enlarged diameter section (11) for the purposes of compartmentalization and mixing of the two compartments (figure 10). Sudo teaches that it is known to use the stopper and enlarged diameter setup as set forth (col 2, ln 15-20), to provide the ability to store, mix, and dispense medicaments effectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection system as taught by Malay et al., with the mixing assembly as taught by Sudo, since such a modification would provide the injection system with a means for effective mixing and dispensing of a medicament.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malay et al in view of Kwee et al. (4,818,517). Malay et al. discloses the claimed invention except for the use of insoluble particles present in the injection system. Kwee et al. teaches that it is known to use insoluble particles as set forth (col 2, ln 10-20) for the purposes of dispensing suspensions or polymeric gels. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the injection system as taught by Malay et al., with a insoluble particle medicament as taught by Kwee et al., since such a modification would provide the injection system with the ability to mix and dispense a particle suspension.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified (Sudo) Malay et al. Malay et al. discloses the claimed invention but

Art Unit: 3763

does not disclose expressly the fixed needle. Sudo shows that it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the injection system as taught by Malay et al. with the fixed, because Applicant has not disclosed that a fixed needle provides an advantage over a movable needle, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a movable needle as taught by Malay et al., because it provides the ability to retract the needle after use and still allows for proper functional use of the injection device and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Malay et al.

Response to Arguments

The amended specification submitted August 31, 2004 to include the disclosure of the "jet injector" is considered new matter by Examiner. Examiner respectfully disagrees with the Applicants remarks submitted August 31, 2005 in that the originally filled abstract submitted November 22, 2002 supports this disclosure. The abstract merely mentions "a medicament cartridge for an injection system" and further continues to mention the structural elements of the embodiments presented by the claims with no reference to said "jet injection." By Applicants own admission that the "jet injector is quite significant structural features" and therefore would label this new matter as the specification is also silent in regards to this term ("jet injector").

Applicant's arguments, see Applicants Remarks, filed August 31, 2004, with respect to the withdrawal of claims 18-22 (drawn the method) and claims 23-

Art Unit: 3763

28 have been fully considered and are persuasive. The withdrawal of claims 18-28 has been withdrawn and are now pending as previously stated.

Applicant's arguments with respect to claims 1-7 (incorrectly numbered as "17" in Applicants Remarks", 9-13 and 15-17 have been considered but are moot in view of the new ground(s) of rejection.

In conclusion the Applicants Remarks also indicate a response to a final status of this application. As currently stands this application is still in a non-final state, this serves as official notice.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takamura, Tanaka et al., Schreuder, Szwarc, Kamstra, Higashikawa, Vetter, and Uemura et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on Monday through Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 22, 2005



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Art Unit 3763